

Pennsylvania Department of Health

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| STATEMENT OF DEFICIENCIES AND<br>PLAN OF CORRECTION (POC)                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | (X1) PROVIDER/SUPPLIER/CLIA<br>IDENTIFICATION NUMBER:<br><br><b>39C0001358</b>                                      | (X2) MULTIPLE CONSTRUCTION:<br><br>A. BLDG: <u>00</u><br>B. WING: _____                                   |                                                                                                                     | (X3) DATE SURVEY<br>COMPLETED:<br><br><b>07/25/2023</b> |
| NAME OF PROVIDER OR SUPPLIER:<br><b>INTEGRATED SURGICAL INSTITUTE, LLC</b><br><br>STATE LICENSE NUMBER: <b>50711501</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | STREET ADDRESS, CITY, STATE, ZIP CODE:<br><b>1001 JAMES DRIVE</b><br><b>Building C</b><br><b>LEESPORT, PA 19533</b> |                                                                                                           |                                                                                                                     |                                                         |
| (X4) ID<br>PREFIX<br>TAG                                                                                                | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY<br>MUST BE PRECEDED BY FULL REGULATORY OR LSC<br>IDENTIFYING INFORMATION)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | ID<br>PREFIX TAG                                                                                                    | PROVIDER'S PLAN OF CORRECTION (EACH<br>CORRECTIVE ACTION SHOULD BE<br>CROSS-REFERENCED TO THE APPROPRIATE | (X5)<br>COMPLETE<br>DATE                                                                                            |                                                         |
| S 0000                                                                                                                  | INITIAL COMMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | S 0000                                                                                                              |                                                                                                           |                                                                                                                     |                                                         |
| S 0150                                                                                                                  | <p>This report is the result of an unannounced revisit survey conducted on July 25, 2023, following a State Licensure survey completed on April 25, 2023, at Integrated Surgical Institute. It was determined that the facility was not in compliance with the requirements of the Pennsylvania Department of Health's Rules and Regulations for Ambulatory Care Facilities, Annex A, Title 28, Part IV, Subparts A and F, Chapters 551-573, November 1999.</p> <p>551.64 Content of plan of correction</p> <p>551.64 Content of Plan of Correction</p> <p>A plan of correction shall address deficiencies cited in the compliance directive of the Department. the plan shall state specifically what corrective action is to be taken, by whom and when.</p> <p>This REGULATION is not met as evidenced by:</p> | S 0150                                                                                                              | The DON and Administrator will report activities to the QAPI committee during quarterly meetings.         | <p>Completion Date:<br/><b>08/30/2023</b></p> <p>Status:<br/><b>APPROVED</b></p> <p>Date:<br/><b>08/11/2023</b></p> |                                                         |
| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                     | TITLE:                                                                                                    |                                                                                                                     | (X6) DATE:                                              |
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| S 0150                                                                                                                  | <p>Continued from page 1</p> <p>Based on review of the facility's Plan of Correction (POC), facility documents, and staff interview (EMP), it was determined Integrated Surgical Institute failed to follow their POC that was submitted to and accepted by the Department with a completion date of June 25, 2023 to correct deficient practices.</p> <p>Findings include:</p> <p>On July 25, 2023, a review of the facility POC revealed, "the Director of Nursing will be responsible for auditing 10 charts per week for 4 weeks to ensure that temperatures are being recorded in PACU (Post Anesthesia Care Unit)."</p> <p>Review of the facilities documentation revealed audits were completed and review of medical records (MR) revealed MR8, MR10, and MR11 had no temperatures documented.</p> <p>Interview with EMP1 confirmed the temperatures were not documented.</p> | S 0150                                                                                                              |                                                                                                           |                          |                                                         |

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| S 0150                                                                                                                  | Continued from page 2<br><br>On July 25, 2023, a review of the facility POC revealed, "New Delineation of Privileges were obtained for all recredentialed providers."<br><br>Review of the facilities credentialing files CF2, CF3, CF4 and CF5 revealed no new Delineation of Privileges were obtained for recredentialed providers.<br><br>Interview with EMP3 confirmed there were no new Delineation of Privileges obtained.<br><br>Cross reference:<br>Discharge Criteria 553.25 (1)<br>Requirements 555.3 (d) (1) | S 0150                                                                                                              |                                                                                                           |                          |                                                         |
| S 3250                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | S 3250                                                                                                              |                                                                                                           |                          |                                                         |

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| S 3250                                                                                                                  | Continued from page 3<br><br>553.25 (1-6) Discharge Criteria<br><br>553.25 Discharge Criteria<br><br>A patient may only be discharged from an ASF if the following physical status criteria are met:<br>(1) Vital signs. Blood pressure, heart rate, temperature and respiratory rate are within the normal range for the patient's age or at preoperative levels for that patient.<br>(2) Activity. The patient has regained preoperative mobility without assistance or syncope, or function at his usual level considering limitations imposed by the surgical procedure.<br>(3) Mental status. The patient is awake, alert or functions at his preoperative mental status.<br>(4) Pain. The patient's pain can be effectively controlled with medication.<br>(5) Bleeding. Bleeding is controlled and consistent with that expected from the surgical procedure.<br>(6) Nausea/vomiting. Minimal nausea or vomiting is controlled and consistent with that expected from the surgical procedure.<br><br>This REGULATION is not met as evidenced by: | S 3250                                                                                                              | The DON re-educated staff on appropriate vital sign monitoring of patients in PACU, including the need to register the temperature readings of each patient on arrival and at discharge.<br><br>The DON will perform 10 nursing chart audits per week for 4 weeks to determine if compliance with vital signs/temperature documentation is occurring.<br><br>All nursing chart audits will be reviewed during the next scheduled QAPI meeting and any deviations will be reported to the governing board. | Completion<br>Date:<br><b>08/30/2023</b><br>Status:<br><b>APPROVED</b><br>Date:<br><b>08/11/2023</b> |                                                         |
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| S 3250                                                                                                                  | Continued from page 4<br><br>Based on review of facility documents, medical records (MR), and staff interview (EMP), it was determined the facility failed to ensure that vital signs were documented prior to discharge for three of the eleven medical records reviewed (MR8, MR10, and MR11).<br><br>Findings include:<br><br>Review of the "Post-Operative Care of the Patient ... The patient must meet discharge criteria prior to discharge from the facility .... Procedure:<br>Thermoregulation: 1. Hypothermia, defined as a core temperature less than 36C, .... c. If normothermic ( >36 C) institute preventative warming measures:<br>... iii. Assess patient thermal comfort level on admission, discharge, and more frequently as indicated. ..."<br><br>Review of MR8 revealed no documentation of temperature prior to discharge. | S 3250                                                                                                              |                                                                                                           |                          |                                                         |

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| S 3250                                                                                                                  | Continued from page 5<br><br>Review of MR10 revealed no documentation of<br>temperature prior to discharge.<br><br>Review of MR11 revealed no documentation of<br>temperature prior to discharge.<br><br>Interview with EMP1 on July 25, 2023, at 10:00<br>AM confirmed there were no temperatures<br>documented in the identified medical records. | S 3250                                                                                                              |                                                                                                           |                          |                                                         |
| S 53D0                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                     | S 53D0                                                                                                              |                                                                                                           |                          |                                                         |

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| S 53D0                                                                                                                  | Continued from page 6<br><br>555.3 (d)(1-2) Requirements<br><br>Granting of clinical privileges shall follow established policies and procedures in the bylaws or similar rules and regulations the procedures shall provide the following.<br>(1) Written record of the application, which includes the scope of privileges sought and granted. The delineation "clinical privileges" shall address the administration of anesthesia.<br>(2) A review, summarized on record with appropriate documentation of the qualifications of the applicant.<br><br>This REGULATION is not met as evidenced by: | S 53D0                                                                                                              | The Center updated the Delineation of Privileges Form. The Governing Board has reviewed and approved the updated application for credentialing/ re-credentialing forms, including the new Delineation of Privileges form for providers and allied healthcare professionals. All providers have received the new forms and are updating their files and requesting privileges.<br><br>The Administrator will utilize a spreadsheet for tracking of credentialing and re-credentialing activities for providers. This will be reviewed by the Administrator on a monthly basis. The information will be provided to the Medical Executive Committee and Governing Board during quarterly meetings. | Completion<br>Date:<br><b>08/30/2023</b><br>Status:<br><b>APPROVED</b><br>Date:<br><b>08/11/2023</b> |                                                         |
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| S 53D0                                                                                                                  | Continued from page 7<br><br>Based on review of facility documents, credentialing files (CF), and staff interview (EMP), it was determined the facility failed to ensure credential files contained the delineation privileges sought and granted for initial appointment or reappointment for facility staff for four of five credentialing files reviewed (CF2, CF3, CF4 and CF5).<br><br>Findings include:<br><br>Review of facilities "Bylaws of the Medical Staff of Integrated Surgical Institute, LLC .... 3.2 Conditions and Duration of Appointment ... C. Privileges Granted in Accordance with Bylaws: Appointment to the Medical Staff shall confer on the appointee only such privileges granted in accordance with these Bylaws and shall be reviewed at each reappointment. ... 6.3 Reappointment Process ... B. Each recommendation concerning the reappointment of a Medical Staff Member and the clinical privileges to be granted upon reappointment shall be based upon the Practitioner's: ..." Policy review of "Physician Credentialing 2.03" revealed "Procedure: | S 53D0                                                                                                              |                                                                                                           |                          |                                                         |



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| NAME OF PROVIDER OR SUPPLIER:<br><b>INTEGRATED SURGICAL INSTITUTE, LLC</b><br><br>STATE LICENSE NUMBER: <b>50711501</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | STREET ADDRESS, CITY, STATE, ZIP CODE:<br><b>1001 JAMES DRIVE</b><br><b>Building C</b><br><b>LEESPORT, PA 19533</b> |                                                                                                           |                          |                                                         |
| (X4) ID<br>PREFIX<br>TAG                                                                                                | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY<br>MUST BE PRECEDED BY FULL REGULATORY OR LSC<br>IDENTIFYING INFORMATION)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | ID<br>PREFIX TAG                                                                                                    | PROVIDER'S PLAN OF CORRECTION (EACH<br>CORRECTIVE ACTION SHOULD BE<br>CROSS-REFERENCED TO THE APPROPRIATE | (X5)<br>COMPLETE<br>DATE |                                                         |
| S 53D0                                                                                                                  | Continued from page 8<br><br>2. The Board of Managers, either directly or by<br>delegation, makes ( in a manner consistent with state<br>law) initial appointment, reappoint, and assignment<br>or curtailment of clinical privileges of medical staff<br>members based on professional peer evaluation ..."<br><br>Policy review of "Privileging 2.04" revealed<br>"Procedure: ... 4. The Board of Managers provides<br>a process ( in a manner consistent with state law and<br>based on evidence of education, training,<br>experience, and current competence) for initial<br>appointment, reappointment, and assignment or<br>curtailment of privileges and practice for allied health<br>care professionals as detailed in the Medical Staff<br>Bylaws ..."<br><br>Review of CF2 revealed no new delineation's of<br>privileges on file.<br><br>Review of CF3 revealed no new delineation's of<br>privileges on file.<br><br>Review of CF4 revealed no new delineation of | S 53D0                                                                                                              |                                                                                                           |                          |                                                         |

Pennsylvania Department of Health

|                                                                                                                         |                                                                                                                                                                                                                                                                               |                                                                                                                     |                                                                                                           |                          |                                                         |
|-------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|--------------------------|---------------------------------------------------------|
| STATEMENT OF DEFICIENCIES AND<br>PLAN OF CORRECTION (POC)                                                               |                                                                                                                                                                                                                                                                               | (X1) PROVIDER/SUPPLIER/CLIA<br>IDENTIFICATION NUMBER:<br><br><b>39C0001358</b>                                      | (X2) MULTIPLE CONSTRUCTION:<br><br>A. BLDG: <u>00</u><br>B. WING: _____                                   |                          | (X3) DATE SURVEY<br>COMPLETED:<br><br><b>07/25/2023</b> |
| NAME OF PROVIDER OR SUPPLIER:<br><b>INTEGRATED SURGICAL INSTITUTE, LLC</b><br><br>STATE LICENSE NUMBER: <b>50711501</b> |                                                                                                                                                                                                                                                                               | STREET ADDRESS, CITY, STATE, ZIP CODE:<br><b>1001 JAMES DRIVE</b><br><b>Building C</b><br><b>LEESPORT, PA 19533</b> |                                                                                                           |                          |                                                         |
| (X4) ID<br>PREFIX<br>TAG                                                                                                | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY<br>MUST BE PRECEDED BY FULL REGULATORY OR LSC<br>IDENTIFYING INFORMATION)                                                                                                                                                  | ID<br>PREFIX TAG                                                                                                    | PROVIDER'S PLAN OF CORRECTION (EACH<br>CORRECTIVE ACTION SHOULD BE<br>CROSS-REFERENCED TO THE APPROPRIATE | (X5)<br>COMPLETE<br>DATE |                                                         |
| S 53D0                                                                                                                  | Continued from page 9<br><br>privileges on file.<br><br>Review of CF5 revealed no new delineation of<br>privileges on file.<br><br>Interview with EMP3 on July 25, 2023, confirmed<br>there were no new Delineation of Privileges<br>obtained for the above referenced files. | S 53D0                                                                                                              |                                                                                                           |                          |                                                         |



# Certified End Page

**INTEGRATED SURGICAL INSTITUTE, LLC**

**STATE LICENSE NUMBER: 50711501**

**SURVEY EXIT DATE: 07/25/2023**

**I Certify This Document to be a True and Correct Statement of Deficiencies and  
Approved Facility Plan of Correction for the Above-Identified Facility Survey**

A handwritten signature in black ink that reads "Jeane Parisi".

*Jeane Parisi*  
*Deputy Secretary for Quality Assurance*

A handwritten signature in black ink that reads "Debra L. Bogen MD".

*Debra L. Bogen, MD, FAAP*  
*Acting Secretary of Health*



THIS IS A CERTIFICATION PAGE

**PLEASE DO NOT DETACH**

THIS PAGE IS NOW PART OF THIS SURVEY